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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
21 CFR Part 1
[Docket No. 2002N–0278]

Guidance for Industry: Questions and Answers on the Interim Final Rule on Prior Notice of Imported Food; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Prior Notice of Imported Food, Questions and Answers." The guidance responds to various questions raised about the section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations that require, beginning on December 12, 2003, prior notice to FDA before food is imported or offered for import into the United States.

DATES: Submit written or electronic comments on the agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Prior Notice Help Desk, phone 1–800–216–7331 or 301–575–0156, or Fax 301–210–0247. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

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FOR FURTHER INFORMATION CONTACT: Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 781–596–7785.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58974), FDA issued an interim final rule to implement section 307 of the Bioterrorism Act. The prior notice regulations require, beginning on December 12, 2003, notification to FDA before food (including animal feed) is imported or offered for import into the United States. This guidance responds to questions raised about the interim final rule on prior notice, and it is intended to help the industry better understand and comply with the regulations.

FDA is issuing the guidance entitled "Prior Notice of Imported Food, Questions and Answers" as a Level 1 guidance. Consistent with FDA's good guidance practices regulation (21 CFR 10.115), the agency will accept comment, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. FDA is under a strict statutory deadline in which to implement these regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received

found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www/cfsan.fda.gov/guidance.html.*

Dated: December 11, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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